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10/539,094

12/19/2005

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EXAMINER

DICKINSON, PAUL W

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

08/20/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/539,094 | Applicant(s) SAWICKA, KIRSTY | |
| | Examiner PAUL DICKINSON | Art Unit 1618 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/3/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of (i) a species wherein the core is an emulsion and (ii) a species wherein the non-expanded material comprising a plasticizer which is a glycol, in the reply filed on 6/9/2008, is acknowledged. Upon further consideration, the Examiner has decided to withdraw the restriction requirement. Claims 1-18 are currently under consideration.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3-6, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Fukui et al (Fukui et al, Studies on applicability of press-coated tablets using hydroxypropylcellulose (HPC) in the outer shell for time-release preparations, *Journal of Controlled Release*, 2000, 68, 215-223; document provided by Applicant). Fukui et al discloses a time-controlled drug delivery system with a core comprising diltiazem

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hydrochloride (a medicament) and an outer shell comprising hydroxypropylcellulose (a non-expanded film material comprising cellulose material) (see abstract; Experimental Section).

Instant Claim 4 is directed to the roughness average of the surface of the outer shell. Instant Claim 5 is directed to the viscosity of the core. Instant Claim 6 is directed to the peak normal force of the core. Although Fukui et al does not disclose all the characteristics and properties of the composition disclosed in the present claims, based on the substantially identical process using identical components, the Examiner has a reasonable basis to believe that the properties claimed in the present invention are inherent in the drug delivery system disclosed by Fukui et al. Because the PTO has no means to conduct analytical experiments, the burden of proof is shifted to the Applicant to prove that the properties are not inherent. “[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer.” *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).” MPEP § 2112, I.

Claims 1-7 and 13-15 are rejected under 35 U.S.C. 102(b) as being unpatentable over US 6228440 ('400). '400 discloses a pharmaceutical formulation containing (a) an

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inert core of sugar, sugar and starch, or microcrystalline cellulose, (b) a drug emulsion layer, and (c) a protective coating which is made of a film-forming material, such as hydroxypropyl methylcellulose, and a plasticizer (see abstract; col 3, line 9 to col 5, line 2; Examples 1-6). Together, (a) and (b) of '400 correspond to an aqueous fondant core as recited in the instant claims. The protective coating (c) corresponds to the non-expanded film material comprising a modified cellulose material.

Instant Claim 4 is directed to the roughness average of the surface of the non-expanded film. Instant Claim 5 is directed to the viscosity of the core. Instant Claim 6 is directed to the peak normal force of the core. Although '400 does not disclose all the characteristics and properties of the composition disclosed in the present claims, based on the substantially identical process using identical components, the Examiner has a reasonable basis to believe that the properties claimed in the present invention are inherent in the pharmaceutical formulation disclosed by '400. Because the PTO has no means to conduct analytical experiments, the burden of proof is shifted to the Applicant to prove that the properties are not inherent. See MPEP § 2112, I.

Claims 1-12 and 14-18 are rejected under 35 U.S.C. 102(e) as being anticipated by WO 02102356 (WO '356; document provided by Applicant). WO '356 discloses a medicinal composition comprising (a) a core in combination with a medicinally effective unit dose of one or more active ingredients; (b) the core being enclosed within a non-expanded film material comprising hydroxypropyl methylcellulose (see abstract; page 2, lines 6-21; Claims 1-14). A fondant core which comprises greater than 50% by weight

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of one or more sugars and less than 50% by weight of water is exemplified (see page 2, lines 23-27). The hydroxypropyl methylcellulose film comprises at least 40% by weight of cellulose material (see col 2, lines 13-15). In one embodiment, the film material comprises 40-80% by weight hydroxypropyl methylcellulose and 20-60% by weight of one or more plasticisers selected from polyethylene glycol, propylene glycols and glycerin (glycerol) (see page 15, line 31 to page 16, line 4; Claims 9-10). The medicinal composition can be prepared by forming a first sheet of hydroxypropyl methylcellulose with a plurality of depressions, placing the material which comprises the core into the depressions, sealing a planar second sheet of hydroxypropyl methylcellulose on top of the first sheet to enclose the core material, and cutting the individual dosage forms of the sheet (see page 17, lines 22-28).

Instant Claim 2 is directed to the porosity of the film. Instant Claim 4 is directed to the roughness average of the surface of the non-expanded film. Instant Claim 5 is directed to the viscosity of the core. Instant Claim 6 is directed to the peak normal force of the core. Although WO '356 does not disclose all the characteristics and properties of the composition disclosed in the present claims, based on the substantially identical process using identical components, the Examiner has a reasonable basis to believe that the properties claimed in the present invention are inherent in the medicinal composition disclosed by WO '356. Because the PTO has no means to conduct analytical experiments, the burden of proof is shifted to the Applicant to prove that the properties are not inherent. See MPEP § 2112, I.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL DICKINSON whose telephone number is (571)270-3499. The examiner can normally be reached on Mon-Thurs 9:00am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Paul Dickinson
Examiner
AU 1618

August 16, 2008

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